REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 8-14 are pending in this application and stand rejected.

Claim 12 is amended to change dependency to claim 11. No new matter has been added by the above claim amendments.

Applicants respectfully request entry and consideration of the present after final amendment. Again, claim 12 is amended only to change its dependency to claim 12 to thereby include subject matter of a previously-pending claim. Applicants believe this change does not present any new issues that would require further search and/or consideration. Also, the traversal presented below addresses the obviousness rejection of record. Indeed, at the very least, it is believed that the present amendment places the application in better condition for appeal.

II. CLAIM OBJECTION

Claims 9 and 12 were objected to as being substantial duplicates for the reasons noted on page 2 of the Office Action. The present amendment overcomes this rejection by amending claim 12 to change dependency to claim 11. Therefore, the objection is untenable and should be withdrawn.

III. WRITTEN DESCRIPTION/NEW MATTER REJECTION

Claims 11 and 14 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification lacks written description for the claims for the reasons on page 3 of the Office Action. This is a new matter rejection. This rejection is respectfully traversed.

Specifically, the Office contends that the deletion of the condition that hydroxyproline and aspartic acid be complexed with silanol is new matter, because the specification only supports hydroxyproline and aspartic acid complexed with silanol. The Office points to the description at page 5, lines 20-30 of the disclosure. Applicants respectfully disagree.

It is true that the specification (for instance, at page 5, lines 20-30) discloses hydroxyproline and aspartic acid complexed with silanol. However, it is believed that the specification also contemplates the use of hydroxyproline and aspartic acid together and not complexed with silanol. In this regard, the specification never discloses that complexation with silanol is a requirement or even necessary in all cases for effectiveness. Indeed, the specification even discusses the effectiveness of hydroxyproline and aspartic acid by themselves (known hair loss treating agents) to treat/delay hair loss. As such, it is believed that the specification reasonably contemplates the combination of hydroxyproline and aspartic acid

together, not complexed with silanol, in the claimed composition for topical administration to treat/delay hair loss. Again, nowhere is it disclosed that complexation with silanol is a requirement.

Thus, it is believed that the specification supports the combination of hydroxyproline and aspartic acid together, not complexed with silanol, in the claimed composition for topical administration to treat/delay hair loss. Therefore, withdrawal of the above-noted written description rejection is requested.

IV. OBVIOUSNESS REJECTIONS

Claims 8-14 were again rejected under 35 U.S.C. § 103(a) as being obvious over DESJONQUERES (US 6,001,378) in view of HIRAMA et al. (US 4,713,397) and ZAVERI et al. (US 6,376,557) for the reasons on page 4 of the Office Action. This rejection is respectfully traversed.

The Office again argues that the claimed composition is directed to a combination of known ingredients all of which were known to treat hair loss.

In reply, Applicants again respectfully submit that one skilled in the art would lack the motivation to combine and modify the teachings DESJONQUERES, HIRAMA, and ZAVERI in manner to obtain the claimed invention as the skilled artisan would lack a reason to pick and choose a) octyl butyrate, b) glutamine peptides, c) hydroxyproline and aspartic acid, d) benzyl

nicotinate, and e) panthenol as present in the claimed invention from the multitude of compositions disclosed in the above-identified publications.

Applicants also argue that one skilled in the art would lack the motivation to obtain a composition with the amounts as claimed. As noted in the last response, a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy).

None of the above-identified publications disclose or suggest that the combination of compounds or recited amounts. Accordingly, Applicants submit that one skilled in the art would not consider the recited amounts as variables which achieve a recognized result.

With respect to Applicants' previous arguments of unexpected and superior results achieved by the synergistic effect of the combined elements at their specific concentrations (i.e., result of effective parameters), the Examiner argues that he is in no position to evaluate alleged unexpected and/or

superior results, since no factual data/evidence was provided to support such.

In reply, Applicants herein provide factual data on the effectiveness of the claimed composition, i.e. a test procedure which proves the superior results against hair loss achieved by the present invention.

First, Applicants would like to point out that the test procedure described herein are replicable in any lab and prove beyond any reasonable doubt the superior results of the claimed composition. Second, it should be noted that the specification does provide factual data of evidence unexpected and superior results. See the discussion on pages 8 and 9. Applicants wonder if the Office has noted said factual data. Third, please note Applicants are considering submitting such data as discussed below in a Rule 132 Declaration in due course.

The effectiveness test of the claimed composition comprises three “steps”:

1. Effectiveness (against hair loss) test for a compound comprising Octylbutyrate plus glutaminpeptide: Composition A.

2. Effectiveness (against hair loss) test for the claimed compound comprising Octylbutyrate plus glutaminpeptide: Composition B.

3. Comparison between Test 1 and Test 2, showing the superior effect of composition B vs. composition A.

1. Effectiveness lab test on the combination of Octylbutyrate + glutaminpeptide (Compound A)

To determine the effectiveness against hair loss of a specified composition, i.e. lotion, Applicants used the method called “fototricogramma”(it.) to analyze the behaviour of the hair in terms of number of units on a surface and the distribution of the percentage of hairs in anagen and telogen phase:

20 male subjects were selected with hair loss problems aged between 18 and 60 years. In a defined area of the scalp of about 5 mm^2, Applicants cut the hair and took digital pictures of the area in order to count the number of hair. After 3 days, pictures were taken of the cut area.

Subsequently, the 20 volunteers received a hair lotion to be applied for 3 months, every day, about 5 ml of lotion by massaging without a rinse. 9 subjects received a placebo, and the other 9 received a lotion containing only Octylbutyrate + glutaminpeptide as active ingredients.

The distribution of lotions (placebo or lotion) was done at random, without informing the volunteer.

After 3 months of treatment, the same area is shaved and photographed and photographed again, 3 days after shaving.

A comparison of images between D0 and D3 and those between D90 and D93 makes it possible to determine the total

number of hair and the number of hairs in anagen and telogen phase.

Before the start of treatment and at the end of the year, the volunteers complete a questionnaire on self-produced and treatment.

The following table summarizes the results:

Average number if hair Of the shaved area (5 mm^2)				
	D0		D90	
	Telogen Phase	Anagen Phase	Telogen Phase	Anagen Phase
Treatment*	11,22	38,33	7,89	42,22
Placebo	6,33	43,56	5,22 **-29.7%**	45,11 **10,15%**

The numbers in bold refer respectively to the percentage reduction of hair in telogen phase and increasing percentage of hairs in anagen phase.

* Lotion containing only Octylbutyrate + Glutaminpeptide as active substances.

It is noted that in 8 out of 9 cases (89%), the number of hairs in the anagen phase and significantly increases the number of hairs in telogen phase decreases in 7 cases out of 9 (average decrease of hair in telogen phase, 30 %).

The changes after use of placebo lotion are not significant.

The analysis of questionnaires self leads to the following observations:

- Treatment group*:

  - The importance of hair loss is strong for 22% of the volunteers, average 67% and close to 11%.

  - After 3 months of treatment with the lotion treatment of the amount of hair seems a little lost in the 44% and average 56%.

  - 67% of volunteers observed a reduction in hair loss.

- Placebo group:

  - The importance of hair loss is average for 66% and close to 33% of them.

  - After 3 months of use of placebo lotion the amount of lost hair does not seem to vary (short for 33% and average 66%). No significant improvement is observed by volunteers.

2. <u>Effectiveness test of the claimed composition- prodotto B</u>

20 persons with serious hair loss problems were selected.

Period	60 days, with applications every other day
Evaluations	At the beginnings, after 7, 15, 30 and 60 days
TESTS	PULL TEST: Clinical Evaluation the strength of the hair pulling in Correspondence of 3 areas of the scalp hair.
	WASH TEST: hair counts lost after a wash in terms standard.

Results:

There was a statistically significant increase in the strength of hair strength (Pull test). This increase is already present after the first month of treatment (+76.4%) and continues to increase throughout the period of application to an increase of +141.2% after 60 days.

There was a statistically significant reduction of hair loss to Wash test. This reduction is already present after the first month of treatment (-40.85%) and continues throughout the period of application to a reduction of 57.3% after 60 days.

% subjects who noted a decrease of the Fall:

after 30 days = 65%

after 60 days = 70%

Following are some percentages of subjects improved in various parameters monitored:

% of the subject with ameliorations PULL TEST

after 30 days = 55%

after 60 days = 85%

% of the subject with ameliorations WASH TEST

after 30 days = 90%

after 60 days = 95%

3. Comparison between the results obtained on hair loss through application of a topical lotion containing only Octylbutyrate and Glutaminpeptide and the claimed composition

Results of subjective evaluation, or % of subjects in each sample which noted a decrease of the fall:

	After 30 days	After 60 days	After 90 days
A			**67%**
B	**65%**	**70%**	

The table shows clearly that the product B (of the formulation of the claimed invention) achieves anti-hair loss effectiveness higher than that obtained with the use of a product, plus some details that validate the effectiveness of exceeds of the wording:

	Prodotto A	Prodotto B
Mode of application	Daily	**Every other day**
Positive results	After 90 days	**After 30 days**
% of subject with ameliorations	67%	**70%**

• Results on the decrease of lost hair (typically the hair in telogen)

Comparison of results on the reduction of hair in telogen phase determined by electronic counts (Product A) and the

Wash Test (Product B); methodologies for the determination are different but the objective is the same.

	After 30 days	After 60 days	After 90 days
Composition A			**-29.7%** reduction in telogen hair
Composition B	**-40.85%** % decrease in the fall (lost in telogen hair) **90%** percentage of subjects improved	**-57%** % decrease in the fall (lost in telogen hair) **95%** percentage of subjects improved	

- Results about the amelioration of hair increase/growth, phase anagen.

Comparison of results on hair in the anagen phase determined by electronic counts (Product A) and the Pull Test (Product B) which is known as giving a measure of tensile strength of hair, usually tied to feature in hair anagen phase; methodologies for the determination are different but the objective is the same.

	After 30 days	After 60 days	After 90 days
Prodotto A			**+10.15%** of hair increase % in anagen phase
Prodotto B	**76.4%**	**141.2%**	

	increase % of the strength (due tot he hair in anagen) **55%** Of the subjects had an amelioration	increase % of the strength (due tot he hair in anagen) **85%** Of the subjects had an amelioration	

4. Conclusions

Assessing the following parameters:

•% subjects who noted a decrease of the fall

•% of subjects improved to PULL TEST (expression of the amount of hair in anagen)

•% subject to improved test WASH (expression of the amount of hair in telogen)

•% increase in resistance (due to hair in anagen)

•% decrease in the fall (linked to hair lost in telogen)

Based on the above, it is believed that the comparison of the results obtained clearly shows that the composition B, which corresponds to the subject matter of the instant application prove a superior efficacy than the product A, which is lotion containing only Octylbutyrate and Glutaminpeptide.

It is believed that such results are evidence of the surprising and unexpected results of the claimed composition over the cited prior art references. Such results are indicative of the non-obviousness of the claims.

Thus, in view of the above, Applicants respectfully request the obviousness rejection be withdrawn.

V. CONCLUSION

Having fully addressed all of the issues raised in the Office Action, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Jay F. Williams/

Jay F. Williams, Reg. No. 48,036
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

JFW/fb